UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

UNITED STATES ex rel. LIUBOV SKIBO, et al., Plaintiffs, v. GREER LABORATORIES, INC., et al., Defendants.	Case No. 5:13-cv-110 (RV)

RELATORS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT GREER LABORATORIES, INC.'S MOTION TO DISMISS
(Oral Argument Requested)

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STATUTES

Relators Liubov Skibo and Edward Patt ("Relators") respectfully submit this Memorandum of Law in Opposition to Defendant Greer Laboratories Inc.'s ("Greer" or the "Company") Motion to Dismiss Realtors' Amended Complaint.[1] Also submitted concurrently herewith is the Declaration of Charles H. Rabon, Jr., one of Relator's counsel, attaching several documents that "are quoted, referenced, and relied upon" in the complaint, see *In re Wachovia Corp.*, No. 3:09cv262, 2010 U.S. Dist. LEXIS 79971, documents obtained from official government websites which are pertinent to the allegations of the complaint, see *Hall v. Virginia*, 385 F.3d 421, 424 & n.3 (4th Cir. 2004) (taking judicial notice of information publicly available on official government website), and documents of which the Court may take judicial notice under Federal Rule of Evidence Rule 201(b)(1)). The Court may consider during Rule 12(b)(6) review any "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322, 127 S. Ct. 2499, 168 L. Ed. 2d 179 (2007).

PRELIMINARY STATEMENT

Relators allege that Greer knowingly manufactured and sold "custom mixes" of allergenic extracts, used for immunotherapy, that were (1) ***unapproved*** and ***unlicensed*** by the U.S. Food and Drug Administration ("FDA"); (2) ***misbranded*** under the Federal Food, Drug and Cosmetic Act ("FDCA"); and (3) ***adulterated*** under the FDCA and regulations thereunder governing current good manufacturing practices ("cGMP"). In doing so, Greer both submitted and caused to be submitted (by others) false claims for payment, which were ineligible for reimbursement under Medicare, Medicaid, or TRICARE, to the federal and state governments.

[1] Citations to "¶ __" herein are to paragraphs of the Amended Complaint (ECF No. 10). Citations to "MTD __" are to Greer's motion to dismiss (ECF No. 41). Citations to "Ex. __" are to exhibits to the Declaration of Charles H. Rabon, Jr., filed herewith.

The Amended Complaint also states claims for retaliation against the Relators in violation of 31 U.S.C. § 3130(h).

In support of its motion to dismiss, Greer argues that Relators' must plead specific individual claims for reimbursement to a federal or state government healthcare program in order to state a claim with the requisite particularity under Fed. R. Civ. P. 9(b). Relators have done more than this, however, by alleging Greer's ***direct*** sales to Offutt Air Force Base ("OAFB"), which was operated by the federal government, and which therefore resulted in direct claims for payment by Greer to the federal government. Moreover, federal regulations mandated that all active-duty patients at OAFB were enrolled in TRICARE (formerly CHAMPUS), which covered allergy treatment. Thus, Greer's direct sales of custom-mix extracts to OAFB necessarily led to claims to the government for reimbursement for any active-duty patients receiving those treatments.

Apart from Greer's actual sales of unapproved drugs, unlicensed biological products, misbranded drugs, and adulterated drugs to OAFB, there is a strong (and most certainly at least a plausible) inference that a substantial proportion of Greer's nationwide sales of illegal custom-mix extracts necessarily resulted in reimbursement claims paid by Medicare because (1) as the leading company in the industry, Greer had as much as a 52% share of the overall U.S. market for allergen immunotherapy; (2) of this share, nearly half of Greer's bulk allergenic extract lots were custom mixes; and (3) Medicare has historically reimbursed hundreds of millions of dollars for allergen immunotherapy. Because Greer's illegal custom mixes dominated the immunotherapy market that Medicare substantially funded with hundreds of millions of dollars, Greer's custom mixes were plausibly funded by claims to Medicare.[2]

[2] Nevertheless, under the established jurisprudence interpreting the False Claims Act, for present purposes the Relator need only allege a single false claim to survive a motion to dismiss. *Harrison v. Westinghouse Savannah*

Greer also argues that the FDA "acquiesced" to Greer's sale of unlicensed custom mixes and condoned such practices "across the industry." None of the regulatory materials Greer cites support this assertion. To the contrary, as Greer's own authorities confirm, the FDA has repeatedly reaffirmed the plain meaning of 21 C.F.R. § 610.17, which states that manufacturers of biological products "may not" combine licensed products "except as a license is obtained for the combined product." For example, Greer cites 1999 FDA guidance instructing manufacturers how to apply for a "***license"*** to manufacture a "***mixture of allergen.***" Greer also cites a 1985 FDA review that directs readers to the regulation governing the "review procedures" used by FDA's "review panel" to "determine [whether] ***licensed*** biological products," including those that "combine two or more . . . active components," are "safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use."

Greer asserts that the FDA "had explicit knowledge" of the Company's "custom mix practices" though its advertisements. But Greer never advertised that it manufactured ***unlicensed*** custom mixes or compounded ***unlicensed*** custom mixes ***without prescriptions.*** To the contrary, Relators allege that Greer purposely concealed that its manufacture of unlicensed custom mixes without prescriptions by misleadingly prefixing its custom-mix product names with "RX" to create the false impression that they were made pursuant to a prescription.[3]

River Co., 176 F.3d 776, 785 (4th Cir. 1999) ("[T]o trigger liability under the Act, ***a*** *claim* actually must have been submitted to the federal government for reimbursement, resulting in 'a call upon the government fisc.'")(emphasis added). The sale to OAFB, and claim for payment by Greer, meets this threshold. In fact, though, Greer also *caused* millions of dollars of false claims to be submitted to the government in reimbursement for the unapproved drugs that it manufactured and sold.

[3] As is set forth near the end of this Memorandum, if the Court were to determine there is any deficiency in the operative Complaint (and Relators contend there is not), Relators request leave to amend. The original Complaint was amended one time, while the case was under seal, to add certain claims against other allergenic extract manufacturers. In a future amended complaint against this defendant, Relators will allege facts showing that when FDA inspectors asked Greer employees if they had prescriptions for custom mixtures with the "RX" product names, the Greer employees replied in the affirmative.

Greer also argues that its actions were at most "honest mistakes" arising from "confusion" in the industry. But even if the plain language of the FDA's regulations were not enough (which it is) Greer was also directly warned by both Relators and the FDA that its custom mixes were illegal. Greer's concealment of its violations by selling bulk custom mixes labelled "RX" confirms its nuanced understanding of its violations and how to conceal them from the FDA.

Greer also challenges the sufficiency of Relators' retaliation claims under the False Claims Act ("FCA"). Relators' claims for retaliation are adequately pleaded, however, because (1) Relators were engaged in a protected activity (they informed their bosses, at minimum, that Greer was operating an unlicensed compounding pharmacy that was violating cGMPs and that the SLIT clinical trials were tainted by false or falsified data, which Relator Skibo reasonably believed could result in false claims violations in the future); (2) Greer knew of their protected activity (Relators reported Greer's licensing and cGMP violations directly to the Company's CEO, CFO, Head of HR, Vice President of Regulatory Affairs and Quality Assurance, and a member of the Board of Directors); and (3) Greer's retaliation against Relators resulted from their protected activity (for internally reporting Greer's violations, Relators were abruptly and simultaneously fired and offered money to keep quiet). These actions by Relators were "efforts to stop 1 or more violations" of the False Claims Act, which they reasonably and objectively believed that Greer was violating *or soon would be violating*.[4] These allegations by the Relators

[4] The defendant has misapprehended the reason for including the SLIT clinical trials allegations. Relator has not contended that Greer has currently submitted (or caused to be submitted) claims connected with SLIT clinical trial deficiencies. Greer was engaged in the SLIT clinical trials in the hope of gaining FDA approval for new drugs and/or a new method of delivery. If the SLIT clinical trials were tainted by undisclosed false or falsified data due to Greer's failure to abide by cGMP, any later FDA approval would also be tainted, and later claims for reimbursement of said drugs could very well violate the False Claims Act in the future because *Greer would have caused those false claims to be submitted*.

of retaliation in the terms and conditions of their employment are more than sufficient under the False Claims Act and relevant case law.

Finally, since Relators' federal claims are co-extensive with their state-law claims, Relators' state-law claims should remain intact.

ARGUMENT

I. Legal Standards

"In considering a motion to dismiss, the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff." *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). To survive a 12(b)(6) motion to dismiss, a complaint must contain sufficient factual allegations that, accepted as true, "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twomblv*, 550 U.S. 544, 570 (2007)); *see also U.S. ex rel. Oberg v. Pa. Higher Educ. Assistance Agency*, 745 F.3d 131, 146 (4th Cir. 2014) ("To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must allege facts plausibly establishing the elements of his asserted cause of action."). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*. 550 U.S. at 556). The Fourth Circuit has made clear that a plaintiff is not required to prove his case at the pleading stage in order to meet this standard:

> *Iqbal* and *Twombly* do not require a plaintiff to prove his case in the complaint. The requirement of nonconclusory factual detail at the pleading stage is tempered by the recognition that a plaintiff may only have so much information at his disposal at the outset. A "complaint need not 'make a case' against a defendant or 'forecast evidence sufficient to prove an element' of the claim. It need only 'allege facts sufficient to state elements' of the claim."

Robertson v. Sea Pines Real Estate Cos., 679 F.3d 278, 291 (4th Cir. 2012) (quoting *Chao v. Rivendell Woods. Inc.*, 415 F.3d 342, 349 (4th Cir. 2005)). Further, because "[t]he purpose of a

Rule 12(b)(6) motion is to test the sufficiency of a complaint", a Rule 12(b)(6) motion "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Butler v. United States*, 702 F.3d 749, 752 (4th Cir. 2012) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999).

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "Rule 9(b) requires that 'some indicia of reliability' must be provided in the complaint to support the allegation that an actual false claim was presented to the government." *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013) (citation omitted). A complaint provides the requisite indicia of reliability where "specific allegations of the defendant's fraudulent conduct necessarily [lead] to the plausible inference that false claims were presented to the government." *Id.*

II. Relators Have Plausibly and Particularly Pleaded that Greer Submitted, and Caused to Be Submitted, False Claims to the United States Government

Four distinct elements must be pleaded to establish liability under 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B): "(1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that involved a claim made to the government for payment." *U.S. ex rel. Ahumada v. NISH*, 756 F.3d 268, 280 (4th Cir. 2014) (quoting *U.S. ex rel. Rostholder v. Omnicare. Inc.*, 745 F.3d 694, 700 & n.6 (4th Cir. 2014) (citing 31 U.S.C. § 3729(a)(1)).

In its motion, Greer suggests "two reasons" for dismissal. MTD 7. First, Greer argues that Relators have "fail[ed] to identify any specific claims for reimbursement actually submitted to the government by Greer or by others due to Greer's actions . . ." *Id.* Second, Greer argues

that even if Relators have identified such "claims for payment, their allegations do not support any inference that Greer knew such claims were false." *Id.* Neither argument has any merit.

A. Greer Submitted and Caused to Be Submitted False Claims to the United States Government at Offutt Air Force Base

1. Greer sold allergy treatments *directly* to the Offutt Air Force Base, and thus, submitted claims *directly* to the United States Government

Greer sold numerous custom mixes directly to OAFB in Nebraska.[5] ¶ 68. OAFB is identified on the Greer Custom Mix Master List as the medical group that ordered a particular custom mix, "OAFB Minor Mold Mix." *Id.* The Custom Mix Master List also lists "OAFB GRASS MIX 50 ML," "OAFB GRASS MIX 50 ML," "RX OAFB MINOR MOLD MIX," and "RX OAFB GRASS MIX." *See* Ex. 1, at 7, 9, and 22.[6] By selling these custom mixes directly to OAFB, Greer submitted false claims "directly to the federal government." ¶ 1.

Greer argues that "Relators do not identify any claims for payment submitted to or by anyone at [OAFB], making it just as likely that custom mixes were provided only where patients paid for the custom mix themselves or had private insurance." MTD 10. This argument misses the point. Because Greer sold OAFB Minor Mold Mix ***directly*** to the U.S. government acting through OAFB, it is irrelevant whether any patient to whom OAFB resold these products later submitted a claim for reimbursement to a federal healthcare program such as TRICARE. In

[5] In 2009, Greer had $71,237.14 in sales within Nebraska, where OAFB is located. ¶ 14 n.4. Greer would not have manufactured a custom mix for its customer but for having received an "order". The fact that OAFB appears on Greer's Custom Mix Master List is solid evidence that Greer did in fact make up custom mixes for OAFB, prefixing the unapproved, unlicensed biologic with the letters "RX", and that Greer submitted claims for payment on those sales to OAFB.

[6] As Greer acknowledges, "[i]n assessing a motion to dismiss, the court may consider documents that "are quoted, referenced, and relied upon" in the complaint. MTD 3 (quoting *In re Wachovia Corp.*, No. 3:09cv262, 2010 U.S. Dist. LEXIS 79971, at *17 n.4 (W.D.N.C. Aug. 6, 2010)). Greer's "Custom Mix Master List" is such a document. ¶ 67.

other words, regardless of how patients at OAFB paid for these drugs, OAFB (and hence, the government) had already purchased them directly from Greer in the first instance.[7]

2. All active-duty patients at Offutt Air Force Base were automatically enrolled in TRICARE, which reimbursed them for allergy treatments

TRICARE (formerly CHAMPUS) is the federally funded healthcare program that provides benefits for active-duty and retired military members and their dependents. ¶ 36. TRICARE excludes from coverage all "unproven drugs, devices, and medical treatments and procedures," which includes any "drug or device [that] cannot be lawfully marketed without the approval or clearance of the [FDA] and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient." *Id.* (citing 32 C.F.R. § 199.4(g)(15)(i)(A) (2010)). The unlicensed, unapproved custom mixes of allergenic extracts were manufactured and sold in violation of 42 U.S.C. §262(a)(1)(A), 21 U.S.C. §355(a) (2010), and 21 C.F.R. §610.17. Thus, any claim submitted to TRICARE for payment of the "RX" custom mixtures constituted an actionable false claim.

Greer's argument that it was "just as likely" that patients at OAFB "paid for the custom mix themselves or had private insurance," MTD 10, ignores that federal regulations required that all ***"[a]ctive duty members"*** are ***"automatically enrolled"*** in ***"TRICARE Prime."*** 32 C.F.R. ¶ 199.7(a)(6)(i)(A). Moreover, since at least 2008, TRICARE has specifically covered allergy testing and treatment.[8] This coverage extended through at least 2015.[9] Indeed,

[7] Greer also sold custom mixes ("UNC TREE MIX 50 ML" and "UNC ENT WEED MIX 50 ML") to the University of North Carolina. *See* Ex. 1, at 5 and 18. These direct sales of unlicensed custom mixes to a state-funded public university violated the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 to -617. ¶¶ 161-63.

[8] *See* Ex. 3 (TRICARE Policy Manual, Ch. 7 § 14.1, Allergy Testing and Treatment (Feb. 1, 2008) ("Services and supplies required in the diagnosis and treatment of allergies are covered.") (available at http://manuals.tricare.osd.mil).

[9] *See* Ex. 4 (TRICARE Policy Manual, Ch. 7 § 14.1, Allergy Testing and Treatment (Apr. 1, 2015) ("Services and supplies required in the diagnosis and treatment of allergies are covered.") (available at http://manuals.tricare.osd.mil).

www.tricare.mil/allergy confirms that "TRICARE covers proven services and supplies needed to diagnose and treat allergies." Ex. 2.[10] Thus, any active-duty patient at OAFB was automatically enrolled in TRICARE, which reimbursed them for allergy treatments.

Accordingly, it is entirely plausible that at least some of the "RX OAFB MINOR MOLD MIX" and "RX OAFB GRASS MIX" that Greer sold to OAFB was the subject of reimbursement claims made to TRICARE. This is all that Rule 12(b)(6) requires. *See Wag More Dogs, LLC v. Cozart*, 680 F.3d 359, 365 (4th Cir. 2012) (holding that plaintiff may "establish 'facial plausibility' by pleading 'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009)).

B. Greer's Custom Mixes Account for Substantial Proportion of the Overall U.S. Market for Allergen Immunotherapy, for which Medicare Has Paid Hundreds of Millions of Dollars

Greer relies on *United States ex rel. Nathan* to argue that plaintiffs must "identify specific custom mix claims submitted for reimbursement" in order to satisfy Rule 9(b). MTD 9 (citing *Nathan*, 707 F.3d 451 (4th Cir. 2013)).[11] *Nathan* held, however, that if "specific allegations of the defendant's fraudulent conduct necessarily led to the plausible inference that false claims were presented to the government," then Rule 9(b) does not require "particularized allegations of specific false claims." *Nathan*, 707 F.3d at 457.[12] Here, there is a highly plausible inference that

[10] "[D]istrict courts routinely exercise their discretion in taking judicial notice of information available on federal and state government websites." *United States v. Garcia*, No. 315CR00040MOCDSC, 2015 WL 7313425, at *2 (W.D.N.C. Nov. 19, 2015) (collecting cases taking judicial notice of information on government websites).

[11] As noted above, Relators have alleged one specific custom mix, "OAFB Minor Mold Mix," that Greer sold directly to the OAFB, and which was inevitably reimbursed by the Government's TRICARE program for active-duty patients.

[12] *Nathan* is further distinguishable because it was an "off-label" case involving possible "off label" sales of certain drugs that were *actually approved for defined on-label uses*. Here, by contrast, there is no "approved" use of the custom mix extracts because the "custom mixtures" themselves are entirely unapproved and unlicensed. There is no approved, on-label use whatsoever for the custom mixtures, because Greer never underwent the biologic drug approval process for them. See 21 C.F.R. §610.17 and the other statutory and regulatory authorities cited herein.

Greer's custom mixes led to false claims presented to Medicare because (1) Greer had a 30%-52% share of the overall U.S. market for allergen immunotherapy; (2) of this share, nearly half of all of Greer's bulk allergenic extract lots were custom mixes; and (3) Medicare has historically reimbursed hundreds of millions of dollars for allergen immunotherapy.

First, Greer has at least "an approximately 30% share of the U.S. immunotherapy market," ¶ 14, and likely ***more than half of the total U.S. market.*** By June 2014, Greer's share of the immunotherapy market appears to have grown to as much as 40% to 52%. According to a June 4, 2014 presentation by ALK[13] at the Jefferies 2014 Global Healthcare Conference, Greer had a "40%" share in the "USA" "Market" for allergy immunotherapy, which serves more than three million patients and generates billing of $2-3 billion.[14] *See* Ex. 5, at p. 6. According to a March 3, 2015 press release by Stallergenes S.A., "GREER is the leader in allergy immunotherapy in the US with a market share of approximately 52%". Ex. 6.[15] According to GlobalData, as of September 2014, Greer held "the largest market share of the US allergen immunotherapy market." Ex.7.[16]

[13] ALK is the parent company of ALK-Abello, which was a named defendant in this action. ¶ 19. ALK is a competitor of Greer in the worldwide allergenic extract market. ALK's estimate of Greer's market share is actually lower than Greer's own estimate of its share.

[14] Jeffries is a respected international banking and investment firm based in London, New York, and Hong Kong, and which sponsors annual international conferences in the Healthcare and Energy sectors attended by most key industry players. See https://www.jefferies.com. Relators request that the Court take judicial notice of information and market data supplied by Jeffries under FRE Rule 201(b)(2) as being facts "not subject to reasonable dispute" because they "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."

[15] Stallergenes S.A. is majority-owned by Ares Life Sciences, which is Greer's parent company. ¶ 15; *see also* Ex. 6 (noting that "Ares Life Sciences" is the "majority shareholder" of Stallergenes S.A.). Further, it is well established that a court may take judicial notice, pursuant to [Fed. R. Evid. 201], of . . . parties' admissions." O'Neal v. Donahoe, 802 F. Supp. 2d 709, 716 (E.D. Va. 2011

[16] GlobalData, a long established London-based data and analytics company, is "a world leading provider of data and analysis for consumer, technology and healthcare businesses." See https://www.globaldata.com. Relators request that the Court take judicial notice of information and market data supplied by GlobalData under FRE Rule 201(b)(2).

Second, custom mixes accounted for a substantial proportion of Greer's business. "Bulk custom mixes" accounted for approximately 45%, 40%, and 52% of the total lots of bulk allergenic extracts that Greer manufactured in 2008, 2009 and 2010, respectively. ¶ 69. In 2009 and 2010, Greer manufactured over a thousand lots per year of bulk custom mixes. *Id.* In 2008 alone, Greer's customers order 324 lots of "Late Tree Mix." ¶ 70.

"The 'Greer Custom Mix Master List' shows the extent to which Greer is engaged in the manufacture and sale of unapproved biological products." ¶ 67. Specifically, the "Custom Mix Master List" lists 2,204 separate entries of customer mixes. *See* Ex. 1. "The list consists of hundreds of custom mixes for which Greer does not have a license to manufacture, sell or distribute." ¶ 67.

Third, allergen immunotherapy is covered by Medicare (and Medicaid and TRICARE), ¶ 26, which has historically reimbursed hundreds of millions of dollars to patients for such treatments. Specifically, according to a February 2006 report by the Office of the Inspector General of the Department of Health and Human Services, "[i]n 2001, Medicare allowed approximately $130 million for allergen immunotherapy and related services." Ex. 8 ("Allergen Immunotherapy for Medicare Beneficiaries"). "By 2003, this amount had grown to $171 million." *Id.*

Hence, given that Greer's custom mixes permeated the same allergenic immunotherapy market that Medicare substantially funded, it is entirely implausible that Greer's custom mixes were not funded in part by Medicare. These "specific allegations of the defendant's fraudulent conduct necessarily led to the plausible inference that false claims were presented to the government." *Nathan*, 707 F.3d at 457.

These allegations are also readily distinguishable from those alleged by the relator in *Nathan*. In *Nathan*, the relator alleged off-label marketing schemes in which physicians, after having received the off-label marketing, could choose whether to prescribe a drug to patients for off-label uses. 707 F.3d at 459-61. Because the drug was FDA-approved for ***some*** uses at the quantities being prescribed by physicians, *id*. at 454-55, the court held that it could not reasonably infer that the physicians' prescriptions must have been for off-label purposes (and not for approved ones, which was also possible), *id.* at 460. Therefore, the court held that "when a defendant's actions, as alleged and as reasonably inferred from the allegations, ***could*** have led, but ***need not necessarily*** have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." *Id.* at 457 (emphasis in original).

Here, Relators' allegations provide far more indicia of reliability than those provided by the relator in *Nathan*, and meet the pleading requirements of Rule 9(b). Unlike *Nathan*, Greer's unlicensed custom-mix allergenic extracts, which were sold in bulk without any patient-specific prescription, were illegal for any purpose. ¶ 31. Hence, there is no possibility that any claim by anyone for government reimbursement for these products could have been anything but false. Moreover, as noted above, Greer's leading market share of U.S. immunotherapy market, combined with Medicare's high historic rates of reimbursement for those same products, and the fact that unlicensed custom-mix products constituted nearly half of Greer's bulk allergen lots manufactured, collectively lead to the plausible inference that false claims were presented to the government for Greer's custom-mix extracts.

III. Greer's Argument that the FDA "Acquiesced" to the Industry's Sale of Custom Mixes Is Without Merit

Greer relies on several FDA regulations and regulatory publications to suggest that the FDA has "apparently acquiesced" to Greer's practice of selling unlicensed and unprescribed custom mixes. MTD 11. As an initial matter, the Court need look no further than 21 C.F.R. § 610.17, which was "enacted in the 1940's," MTD 12, to conclude that it has always been the FDA's position that "[l]icensed products may not be combined with other licensed products" or with "nonlicensable products" unless "a license is obtained for such combination," 21 C.F.R. § 610.17. As discussed below, none of the regulatory materials Greer cites supports a different conclusion.[18] Rather, they confirm that this has never been legal and that the FDA requires that such products (including combinations of approved, licensed products) must undergo the thorough new drug testing and approval process before being licensed for sale. See http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194562.htm (FDA webpage entitled "What is the approval process for a biological product?" which states in part: "In general, biological products that are used to treat or prevent diseases, like traditional drug products, have to be thoroughly tested and shown to be safe and effective in order to enter interstate commerce in the United States.").

First, Greer cites certain "FDA Guidance issued in 1999" that it argues "makes clear that custom mixes were . . . contemplated and consistent with § 610.17." MTD 13 (citing Ex. 13 1999 Guidance). To the contrary, this 1999 Guidance sets forth "the content and format . . . of a Biologics License Application for an Allergenic Extract." *Id.* at 1 (see footnote 1). In the guidance, the FDA explained that a manufacturer (like Greer) that is applying for a Biologics

[18] There simply is no pronouncement by Congress or by the FDA that it is, or has ever been, "OK" to manufacture and sell unlicensed, unapproved custom mixtures of allergenic extracts. All statements by Congress and the FDA, including recent guidances, and the 483's and Warning Letters issued to Greer and its competitors, are to the contrary.

License Application (BLA) must include detailed information about the "source material" (the "active substance") of an "allergen or allergen mix" for which it seeks a license. *Id.* At p. 4.[19] If Greer had followed this guidance since 1999, it would have avoided the violations and resulting false claims at issue in this case.

Second, Greer cites an "Implementation of Efficacy Review" in 1985 by an "FDA Allergenics Panel" that it claims "indicates that the Panel was well aware that allergenic extract manufacturers had long marketed various mixtures of extracts, including extracts that were not based on individual prescriptions." MTD 13-14 (citing Implementation of Efficacy Review, 50 Fed. Reg. 3082, 3107-08, 3283-85 (Jan. 23, 1985)). Relators do not suggest, however, that it was ever illegal to market ***licensed*** allergenic mixtures without a prescription. Critically, nothing in this review implies or suggests that it was ever legal to manufacture and sell ***unlicensed*** allergenic mixes without prescriptions – Greer's violation, which resulted in the submission of false claims by Greer and others. To the contrary, while the FDA acknowledged that a "fixed-combination extract" (i.e., not prepared by prescription) could be used for therapy, the FDA stressed that "[a] fixed-combination extract is subject to the specifications under [21 C.F.R.] § 601.25(d)(4)" – the specifications for the product to be ***"licensed."*** *Id.* at 3285. Specifically, 21 C.F.R. § 601.25 sets forth the "[r]eview procedures to determine that ***licensed*** biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use." *Id.* (emphasis added). Section 601.25(d) required the FDA's "advisory review panel" to "apply [certain] standards to determine that a biological product is safe and

[19] For example, the FDA informed BLA applicants that "[e]ach lot of source material should be assayed for identity, purity, and potency using validated in-house analytical procedures . . ." *Id.* at 5. For "biological materials," the FDA required details of the "genus and species" *id.*; for "mold source materials," the FDA required a "description . . . sufficient to insure the purity [and] identity through microscopic examination," *id.* at 6; and for "Synthetic Chemical Substances that may Represent Complex Mixtures (e.g., synthetic polymers)" the FDA required "[d]etailed information regarding the source, processing and specification of these substances," *id.* at 8.

effective and not misbranded." For combined biological products, the review panel analyzed the following to determine whether licensing was appropriate and under what terms:

> A biological product may combine two or more safe and effective active components: (i) When each active component makes a contribution to the claimed effect or effects; (ii) when combining of the active ingredients does not decrease the purity, potency, safety, or effectiveness of any of the individual active components; and (iii) if the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent preventive therapy or treatment for a significant proportion of the target population.

21 C.F.R. § 601.25(d)(4). Thus, Greer's suggestion that the 1985 "Efficacy Review" reflected an "industrywide belief that custom mixes were properly manufactured without separate licenses," MTD 13, is directly contradicted by the fact that this document directed readers to the FDA's detailed regulatory requirements for determining whether a combination of two biological products was sufficiently safe to be "***licensed.***" The 1985 Implementation of Efficacy Review was not a tacit repeal of any regulation and particularly not a repeal or relaxation of 21 C.F.R. § 610.17.

Third, Greer cites an expired 1973 regulation that merely refers to manufacturing safety tests for certain "dilutions or mixtures" of biologic products. MTD 12 (citing 21 C.F.R. § 680.3(b)(1)). But Relators do not suggest that ***all*** biologic "mixtures" are ***per se illegal***, rather that a license or prescription is required to manufacture and sell them legally. The fact that the FDA requires that biologic mixtures must be tested for safety in the manufacturing process says nothing as to whether or not the FDA has acquiesced in the unlicensed sale of unapproved, unlicensed mixtures in violation of 21 C.F.R. § 610.17.

Fourth, Greer cites certain "Draft Guidance" from 2015 in which the FDA reaffirmed that "a biological product that is mixed . . . outside the scope of an approved BLA is considered an unlicensed biological product" and in which the FDA was (apparently for the first time)

considering making an exception to this by inviting commentary on "the conditions under which FDA does not intend to take action for [such] violations . . . ." Ex. 10 (80 Fed. Reg. 8881 (Feb. 19, 2015). Based on this, Greer suggests that "it was not until 2015 that FDA first 'made clear' that it was impermissible to manufacture custom mixes without a separate license for each mix." MTD 12. This is simply not true because, as noted above, under 21 C.F.R. § 610.17, which has been virtually unchanged for decades, the FDA has plainly, clearly, and unequivocally required that mixtures of biologics must be separately licensed and the FDA has never waivered from nor contradicted that requirement.[20]

IV. Greer's Argument that the FDA Had "Explicit Knowledge of Greer's Custom Mix Practices" Is Without Merit

Greer argues that the "FDA had explicit knowledge of Greer's custom mix practices" because "Greer publicly advertised its manufacturing and sale of custom mixes." MTD 14-15. This misses the point. As noted above, it is not illegal for a manufacturer to sell a custom mix ***with a license***, ¶ 41, nor for a compounding pharmacy to create a custom mix ***pursuant to a prescription***, ¶ 31. Relators do not allege and Greer does not assert than the Company ever advertised that it manufactured ***unlicensed*** custom mixes or that it compounded ***unlicensed*** custom mixes ***without prescriptions.*** Quite the contrary, Greer actively obscured the fact that its manufacture of unlicensed custom mixes without prescriptions by using a misleading "RX" prefix for most of its custom-mix product. ¶ 60. Indeed, it took a ten-day inspection of Greer's facilities by the FDA (after Relators had raised the issue of Greer's regulatory violations broadly

[20] The Draft Guidance was among several guidance papers issued by FDA following the New England Compounding pharmacy tragedy, see https://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis, and after the present False Claims Act lawsuit was brought. Soon after the filing of this *qui tam* action, FDA inspectors were sent and conducted an inspection at Greer between November 5 – 15, 2013, which resulted in an FDA Warning Letter for, *inter alia*, manufacturing custom mixtures in violation of 21 C.F.R. § 610.17. These are material facts that will be pleaded in a future amended pleading, should the Court determine that the current complaint is deficient in any respect and grant leave to amend. See Section VIII, below.

within the Company, ¶¶ 89-91) to uncover the Company's misconduct. *See* Ex. 11. When the FDA did uncover the misconduct, it issued a Warning Letter. *See* Ex. 12.[21] Furthermore, to the extent Greer is attempting to revive a "government knowledge defense" to scienter – which most certainly, at the least, is premature – the Court should note that this can only be premised on full disclosure by a defendant to the government of the actual true facts of action. See *United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284 (2002)(holding that prior government knowledge of an allegedly false claim can negate the scienter required for an FCA violation when the government has ***full knowledge of the relevant facts***)(emphasis added).[22]

V. Relators Have Sufficiently Pleaded That Greer Knowingly Sold Unapproved and Unlicensed Allergy Treatments

"The [FCA's] scienter requirement defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996, 195 L. Ed. 2d 348 (2016) (quoting 31 U.S.C. § 3729(b)(1)(A)). Here, Greer also argues that its actions were at most "honest mistakes" arising from "confusion" in the industry, and that as a result, Relators allegations do not support an inference of Greer's Scienter. MTD 15. As noted above, however, Greer does not – and cannot – point to any authority where the FDA has ever condoned the

[21] The Court may take judicial notice of the FDA's Form 483 and Warning Letter to Greer, which were posted on the FDA's website at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm388501.pdf and http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm395263.htm, respectively. *See, e.g.*, *Garcia*, 2015 WL 7313425, at *2; *In re Digitek Prod. Liab. Litig.*, 821 F. Supp. 2d 822, 828 (S.D.W. Va. 2011) (taking judicial notice of statements on FDA's website that satisfied Fed. R. Evid. 201(b)(2)); *see also* Fed. R. Evid. 201(b)(1)) (allowing court to take judicial notice of a fact "not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned").

[22] In the present case, full knowledge would exist if, for example, Greer informed the government: *"We intend to manufacture and sell allergenic mixtures in violation of 21 C.F.R. § 610.17, and to not obtain a license for the combined product – oh, and these will not be for patient-specific prescriptions... FDA, are you OK with that?"* And if a responsible official with authority to bind the government answered *"Yes"*, then a government knowledge inference to negate scienter could be presented to a jury.

manufacture and sale of unlicensed, unprescribed mixed allergen immunotherapy products. To the contrary, 21 C.F.R. § 610.17 has been on the books for decades, informing manufacturers of biological products that they "may not" combine licensed products "except as a license is obtained for the combined product." Moreover, the FDA has repeatedly reaffirmed this licensing requirement at every opportunity. *See, e.g.*, Ex. [1999 Guidance] at 1; 50 Fed. Reg. 3082, 3285 (citing 21 C.F.R. § 601.25(d)(4)). As the leader in allergy immunotherapy with the largest market share of any company, it is simply implausible that Greer could be unaware of this.[23] Moreover, as discussed below, Greer was ***directly warned*** by Relators and the FDA, and yet took affirmative steps to conceal its violations by misleadingly labelling its bulk custom mixes to appear as if they were sold by prescription.

A. Relators warned Greer that the Company's custom mixes were unlicensed and adulterated

During their tenure at Greer from 2008 to 2012, Relators personally informed numerous senior Greer executives – including the CEO, ¶¶ 82, 90; the Vice President of Regulatory Affairs and Quality Assurance, ¶ 82; the CFO and Head of HR, ¶ 89, and a member of the Board of Directors, ¶ 87 – about the Company's regulatory and compliance violations concerning its "custom mix" allergy treatments.

B. The FDA warned Greer that the Company's custom mixes were unlicensed and adulterated

On November 15, 2013, the FDA issued to Greer a Form 483 detailing its "Inspectional Observations" following an inspection of Greer's facilities in Lenoir, NC, during November 5 to

[23] Indeed, in the 1986 Senate Judiciary hearings on the False Claims Act, when discussing the scienter requirements and the "deliberate ignorance" standard, Richard P. Kusserow, Inspector General, Department of Health and Human Services, testified that holding violators accountable for false claims under the deliberate ignorance standard "*has the primary objective of reaching those who play 'ostrich'; that is, those who avoid finding out the true facts underlining their claims, or the content of the applicable rules and regulations, and then seek to hide behind their ignorance*." See https://www.justice.gov/sites/default/files/jmd/legacy/2014/02/09/hear-48-1986.pdf, at transcript p. 198.

15, 2013. *See* Ex. 11, at p. 1. In the Form 483, the FDA informed Greer, in its foremost observation that ***"[p]roduct is not manufactured as described in the approved license application"*** in that ***"[c]ustomers place orders for custom compounded lots, which are composed of a mix of standardized/non-standardized allergenic bulk extracts. The custom orders are not linked to specific patients."*** *Id*. (emphases added).

The FDA also informed Greer that it had ***"[f]ail[ed] to perform an approved general safety test . . . [f]or custom mixed lots"*** during 2012 and 2013. *Id.* (emphasis added). The FDA found that Greer had failed to adequately investigate complaints related to custom-mixed allergenic treatments. For example, the FDA informed Greer that ***"Comprehensive Mix lot # 202479,"*** which contained ***"approximately 20 different Greer allergenic extract components,"*** had caused one patient to experience ***"urticarial, angioedema, wheezing, dyspnea, and anaphylaxi[s] after use . . . ."*** Ex. 11, at p. 5(emphases added). Because there are no FDA-approved mixtures of allergenic extracts of different classes, ¶ 31, this 20-component mix was illegal.[24]

On April 21, 2014, the FDA sent a Warning Letter to Greer's CEO, John Roby, concerning the "significant deviations" and "objectionable conditions" observed during its November 5-15, 2013 inspection of the Company's Lenoir, NC facility. The FDA's primary concern communicated to Mr. Roby was:

[24] The FDA also found that Greer had completely failed to investigate numerous "adverse reactions" by patients to its allergenic extracts, including (1) the "death of a . . . patient following administration of allergenic extract" ("no investigation report"); (2) "severe swelling under tongue" ("not investigated"); (3) a "swollen area with red discoloration" ("not investigated"); and (4) "upper arm pain, erythema, necrotic tissue" ("not investigated"). Ex. 11, at pp. 6-7. Such adverse reactions – particularly in cases of unlicensed, unprescribed mixes of multiple allergens administered together – underscore the importance of "adequate competency and training of those preparing allergens and administering the immunotherapy," particularly given the "significant risk for life-threatening anaphylaxis" recognized by the American Academy of Allergy, Asthma and Immunology. ¶ 25.

> 1. You failed to manufacture drug products in the manner described in your approved [biologics license application].[25] ***You combine various types and amounts of your licensed allergenic extracts to produce allergenic "custom mixtures;" however, you have not obtained a license to manufacture and distribute these combined product mixtures, as required by 21 CFR 610.17.***

Ex. 12 at p. 1 (emphasis added). The FDA emphasized that Greer's manufacture and sale of "custom mixes" violated 21 CFR 610.17:

> **Form FDA 483 observation #1**
> Your response of December 8, 2013 explains that Greer has manufactured Custom Mixes for some time. ***Please note that the sale of these "custom mixes" violates 21 CFR 610.17, and should not continue without approval of each custom mixture manufactured under a BLA.*** You explain that FDA has long permitted the preparation of such mixes in response to a physician's order. ***Regardless of whether or not FDA has objected to the manufacture of prescription sets after receipt of a physician's prescription for a specific patient, the FDA investigator noted that Greer's current manufacture of these mixes is not linked to specific patients or a prescription.***

Id. at p. 3(emphasis added).

C. Greer prefixed its custom mixes with "RX" to create the illusion that the mixtures had been prescribed by a physician

Greer knew the laws and regulations that governed its business, and as a result, took steps to create the illusion that its custom mixes had patient-specific prescriptions. As noted above, Green prefixed many of its custom-mix product names with "RX" (the universal abbreviation for "prescription") to create the illusion that those mixtures were made pursuant to a prescription for individual patients – when in fact they were not. ¶ 60; *see also* Ex. 14, at p. 4. For example, Greer's "Early Tree Mix" and "Late Tree Mix" were present on the Company's "Custom Mix Master List" as "RX AAMC EARLY TREE MIX," "RX AAMC LATE TREE MIX." ¶ 67; *see also* Ex. 1 (listing custom-mix extracts with "RX" prefixes).

[25] Allergenic-extract manufacturers are limited to manufacturing and selling only those extracts which are licensed under a valid and current Biologics License Application ("BLA") that has been approved by the FDA. ¶ 29 (citing 42 U.S.C. §262(a)(1) (A) (2010)). With "very limited exception" of a few "BLA-approved mixes," ¶ 54, "Greer's BLA does not cover [its] custom mixtures, and these mixtures have not been approved by the FDA," ¶ 57.

VI. Relators Have Sufficiently Pleaded Retaliation Under the FCA

To plead an FCA-based retaliatory discharge claim, a plaintiff must allege facts that under *Iqbal*, 556 U.S. at 678, "plausibly suggest an entitlement to relief" because they were (1) "engaged in 'protected activity'"; (2) their "employer knew of these acts"; and (3) their "employer discharged [them] as a result of these acts." *Eberhardt v. Integrated Design & Constr.*, 167 F.3d 861, 866 (4th Cir. 1999) (citing 31 U.S.C. § 3730(h)) (internal citation omitted). In contrast to an FCA-based cause of action for false and fraudulent claims, the specificity requirements of Rule 9(b) do not apply. *United States ex rel. Elms v. Accenture LLP*, 341 Fed. Appx. 869, 873 (4th Cir. 2009). Rather, a "plaintiff need only satisfy Rule 8's notice pleading requirements to survive a motion to dismiss." *Id.*[26]

Here, Relators have plausibly pleaded an entitlement to relief for their FCA-retaliation claim. ***First***, Relators have sufficiently pleaded that they were engaged in a "protected activity." In that regard, "[c]ourts have interpreted FCA–protected activity broadly to cover not only the filing of a *qui tam* suit but also a variety of actions aimed at ascertaining whether or not a fraud has been committed that would give rise to a possible FCA suit." *Id.* "Protected activity" includes not only activity that would support an actual *qui tam* action, but also activity which is part of an effort to stop a present or future FCA violation. See *Carlson v. DynCorp Int'l, LLC*, 2016 U.S. App. LEXIS 15376 (4th Cir. August 22, 2016).[27] Here, Relators' FCA claim concerns

[26] The Court's analysis in *Elms* is instructive as to the relatively limited factual pleading necessary to state a viable retaliation claim, rather than one for false and fraudulent claims: "Elms has alleged that he took action in furtherance of a qui tam suit, that his employer knew of these actions, and that he was terminated as a result. These allegations are sufficient to put defendant on notice of the nature of plaintiff's retaliation claim and therefore survive dismissal under Rule 12(b)(6)." *Id.* at 873-74.

[27] The *Carlson* Court wrote that it would "assume, without deciding, that Carlson is correct in arguing that the second prong of § 3730(h) makes "efforts to stop 1 or more violations" protected activity where those efforts are motivated by an objectively reasonable belief that the employee's employer is violating, or soon will violate, the FCA," but then went on to cite seven circuit court opinions supportive of that position, including three from the Fourth Circuit arising under the ADEA or ADA. *Carlson*, p. 10.

the fact that Greer's compounding pharmacy and custom mix business was manufacturing "adulterated drugs," ¶ 75, by employees that were not "licensed pharmacists," ¶ 55. This is precisely the misconduct that Relators reported to their supervisors. *See, e.g.*, ¶¶ 82 (Skibo reported that "Greer's compounding pharmacy was not duly and properly licensed . . . as a compounding pharmacy in most states"); ¶ 90 (Relator Patt "raised issues to his superiors, including [CEO] John Roby, regarding retention samples" in "the company's custom mix business").[28] Further, Relator Skibo's concerns and complaints related to cGMP deviations and violations associated with SLIT clinical trials – which she reported to and raised with Greer management – were based on her objectively reasonable beliefs that if SLIT were approved by the FDA, then Greer would soon be violating (or cause others to violate) the FCA due to false or falsified data underlying the clinical trials. See *Carlson v. DynCorp Int'l, LLC*, at pp 7-10.

Second, Relators have sufficiently pleaded that Greer knew of their protected activity. As senior managers in "Regulatory Affairs" and "Compliance" with five decades of collective experience in the pharmaceutical industry, ¶¶ 21-22, Relators Skibo and Patt both complained directly to Greer's CEO, John Roby, regarding the Company's regulatory and compliance violations, ¶¶ 82, 90, and Skibo with regard to cGMP violations in connection with the SLIT clinical trials, ¶¶ 80, 81. Indeed, Relator Skibo also complained to her immediate supervisor, the Vice President of Regulatory Affairs and Quality Assurance, ¶ 82, to Greer's CFO and Head of HR, ¶ 89, and even to a member of the Company's Board of Directors, ¶ 87.

Third, Relators have sufficiently pled that Greer's retaliation against them resulted from their protected activity. On May 21, 2012, Relators Skibo ***and*** Patt were ***both*** abruptly fired at once. ¶ 91. In their letters of termination, Greer offered to pay Relators Skibo and Patt

[28] These were the same violations that the FDA discovered in its 2013 inspection. *See* Ex. 11, at p. 1 (finding that "custom compounded lots" were "not manufactured as described in the approved license application" and "reserve samples are not maintained for custom mixed lots").

substantial compensation in exchange for a confidential Release and Covenant Not to Sue Agreement. *Id.* This agreement would have barred them from bringing *any type* of legal claim "arising out of or related to . . . the business activities, dealings, affairs, operations, or assets of [Greer] . . . [and] any claims for . . . violation of public policy . . . .", which plainly would have included an action under the False Claims Act.[29] *Id.* Both Relators refused to sign these agreements or to accept the money that Greer offered them. *Id.*

Defendants further argue that Relators have not sufficiently alleged that the cGMP and manufacturing issues that Relators reported to their superiors "were connected to any type of fraudulent activity." MTD 19. Relators did not only report cGMP and SLIT clinical trials violations, but also that Greer was "not duly and properly licensed in all the states in which it was selling compounded prescriptions." ¶ 82. Moreover, after Relators were both fired in 2012 for reporting Greer's violations internally, ¶ 91, the FDA inspected the Company's facilities in 2013 – in fact the FDA inspectors were specifically on the lookout for the conduct alleged in the *qui tam* complaint, and later issued a 483 and a Warning Letter as to such violations.[30] The FDA's findings confirm that not only Greer was operating outside its "approved license," but also that the Company's cGMP violations involved the same unlicensed custom-mix allergenic extracts for which it submitted (and caused others to submit) false claims.[31] Thus, Greer's licensing and cGMP violation were inextricably intertwined. These allegations are sufficient at

[29] By the date of the Relators' terminations, it was well established that a broad release would have barred a future *qui tam* action. See U.*S. ex rel. Radcliffe v. Purdue Pharma L.P.*, 600 F.3d 319 (4th Cir. 2010).

[30] This, again, is a fact that (if necessary) will be pleaded in an amended complaint.

[31] *See, e.g.*, Ex. 11, at p. 1 ("custom mixed lots . . . were not tested for general safety"); *id.* at 2 ("Custom Mixed lot AASC Weed-1 Mix A lot # 208189 failed"); *id.* at 3 ("no defined speed or time for mixing custom orders"; "mixing step has not been validated"); *id.* at 3-4 ("[f]acilities designed to prevent contamination or mix-ups" are "not free of infestation by rodents, birds, insects, and other vermin"); *id.* at 4 (noting "alarming trend of living insect sightings" and "various types of pests"); *id.* at 5 (patient experienced "urticarial, angioedema, wheezing, dyspnea, and anaphylaxi[s] after use of custom mix").

the pleading stage to state a claim for retaliation. *See Elms*, 341 Fed. Appx. at 873 ("Courts have interpreted FCA-protected activity broadly").

VII. To the Extent Relator's Federal Claims Survive, their State Law Claims Also Survive

Defendants rely on *United States v. Takeda Pharm. Co.*, Nos. 10-11043-FDS, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012), in which the court held that relators had not adequately alleged their underlying federal FCA claim, to argue that Relator's state-law claims should be dismissed. MTD 16. Unlike *Takeda*, Relators' Amended Complaint plainly meets all of Greer's challenges. Because Relators' federal claims are co-extensive with their state-law claims and because the state Medicaid programs provide coverage for allergen immunotherapy, their state-law claims also should remain intact.

VIII. Leave to Amend Should Be Granted

Although Relators believe that they have more than adequately stated their claims, if the Court determines that the Amended Complaint is deficient in any respect, Relators respectfully request leave to replead. *See Foman v. Davis*, 371 U.S. 178, 182 (1962) ("Rule 15(a) declares that leave to amend 'shall be freely given when justice so requires'; this mandate is to be heeded."); see *also Harman v. Unisys Corp.*, 356 Fed. Appx. 638, 641 (4th Cir. 2009) (holding that "district court should have allowed Harman an opportunity to refine her . . . claims by amending her complaint, rather than dismiss those claims with prejudice") (citing to *Ostrzenski v. Seigel*, 177 F.3d 245, 252-53 (4th Cir.1999) (recognizing that rather than dismiss a defective pleading with prejudice, a plaintiff should "be given every opportunity to cure a formal defect in his pleading[,] . . . even though the court doubts that plaintiff will be able to overcome the defects"). Given material developments that have occurred since the complaint was originally filed, including the FDA inspections, issuance of a 483 and Warning Letter to Greer, as well as

similar letters to Greer and other allergen manufacturers (which further included "Untitled Letters")[32] – each of which expressly reaffirmed the FDA's long standing position that manufacturing and selling unlicensed, unapproved custom mixtures is unlawful – it would be entirely appropriate, in the interest of justice, and not futile, for the Court to permit Relators to amend their complaint.

CONCLUSION

For the foregoing reasons, Relators ask this Court to deny Greer's motion in its entirety. In the alternative, should the Court determine that any part or any allegations of the current operative complaint are deficient in stating claims under the False Claims Act, then Relators respectfully request leave to amend and replead.

[32] See Exhibits 15 and 16. Exhibit 15 is an FDA Untitled Letter sent to Greer's competitor, Allergy Laboratories, Inc., on April 3, 2015, admonishing that company that it may not market and promote the sale of unlicensed, unapproved custom mixtures in violation of 21 C.F.R. 610.17. Exhibit 16 is a series of identical letters sent to every allergenic extract manufacturer in the United States. Footnote 1 in each letter admonishes each company that they may not manufacture, promote, and sell unapproved, unlicensed custom mixes: *"Under 21 CFR 610.17, licensed biological products must not be combined with other licensed biological products "either therapeutic, prophylactic or diagnostic," except as covered by a license obtained for the combined product. All mixes of allergenic extracts, including custom mixes, must be subject of an approved biologics license application or have in effect an investigational new drug application."*

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered CM/ECF participants as identified on the Notice of Electronic Filing (NEF) and a paper copy will be sent by certified mail, return receipt requested, to those indicated as non-registered participants as follows:

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